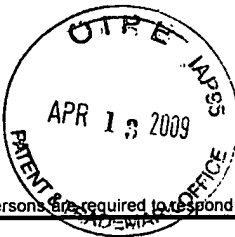


Doc Code: AP.PRE.REQ



PTO/SB/33 (07-05)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

MSDI-223/PC444.06

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on April 10, 2009

Signature

Typed or printed name

Brad A. Schepers

Application Number

10/756,970

Filed

January 13, 2004

First Named Inventor

Kevin T. Foley

Art Unit

3733

Examiner

Mary C. Hoffman

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒

attorney or agent of record.

Registration number 45,431

☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____

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Telephone number

April 10, 2009

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

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*Total of _____ forms are submitted.

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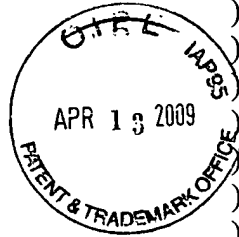
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:
Kevin T. Foley et al.

Application Serial No. 10/756,970

Filed January 13, 2004

SURGICAL INSTRUMENTATION AND
METHOD FOR TREATMENT OF THE SPINE



) Before the Examiner
) Mary C. Hoffman

) Group Art Unit 3733

) Ref. No. MSDI-223/
) PC444.06

) April 10, 2009
)

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the final Office Action dated December 26, 2008 and the Advisory Action dated March 24, 2009, please consider the following. A Notice of Appeal and form PTO/SB/33 Pre-Appeal Brief Request for Review are submitted herewith along with the requisite appeal fee under 37 CFR 41.20(b)(1). Additionally, a request for a one-month extension of time including the requisite fee of \$130 is submitted herewith, thereby extending the time period for responding to the final Office Action and the Advisory Action to April 26, 2009. Please charge any additional fees which may be necessary to Deposit Account No. 12-2424, but not to include any payment of issue fees.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

April 10, 2009

Date of Deposit

Brad A. Schepers

Name of Registered Representative

Signature

April 10, 2009

Date of Signature

The Advisory Action mailed March 24, 2009 entered the previous response to the final Office Action, but indicated that the response did not place the application in condition for allowance. Claims 66-70 and 94-103 were indicated as allowed, and the objection to the drawings and the claim rejections based on 35 USC §112, first paragraph, were withdrawn. However, the rejection of claims 55-63, 65, 68 and 74 as being unpatentable over U.S. Patent No. 5,522,790 to Moll et al. (hereafter “Moll”) and withdrawal of claims 71-73 were maintained.

Independent claim 59 has been solely rejected as being unpatentable over Moll. The final Office Action asserts that the instrument illustrated in Figures 12F and 12G of Moll includes a deformable distal end portion that is outwardly deformed to “define transverse projections, each of the transverse projections arranged along a single transverse axis”, and . . . extends in a uni-lateral direction aligned with the single transverse axis”. (See page 4, lines 2-6; emphasis added). The final Office Action admits that “Moll et al. does (sic) not explicitly teach two oppositely spaced transverse projections”, but nevertheless asserts that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the Moll et al device with two, oppositely spaced projections, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art”. (See page 6, lines 3-7). The Applicant submits that the grounds of rejection set forth in the final Office Action with regard to independent claim 59 do not establish a *prima facie* case of obviousness.

As shown in Figures 12F and 12G of Moll, the endoscope 201 comprises a tubular optical assembly 203 like those used in conventional optical/video endoscopes, and an expandable retractor 223 including a fixed hub 225 and a slidable hub 227 that are interconnected by a plurality of strips or wires 229. The retractor 223 is expanded from the collapsed condition illustrated in Figure 12F to the expanded condition illustrated in Figure 12G by sliding the slidable hub 227 axially along the optical assembly 203, which in turn causes the strips 229 to move radially outwards to form the spherical-shaped expanded structure shown in FIG. 12G. Moll teaches that “[i]n its expanded condition, the expandable mechanical retractor retracts organs obstructing the field of view from the distal end of the optical assembly” and that the expanded retractor “retracts organs or tissues that would otherwise obstruct the view from the optical assembly”. (See column 23, lines 62-64 and column 24, lines 7-9; emphasis added).

As an initial matter, Moll discloses an endoscope configured to retractor organs or soft tissues to provide a work space or field of view for observing adjacent organs or tissues, and not to bear against vertebral bone and uni-axially displace a spinal structure, as recited in

independent claim 59. In the illustrated embodiment of the endoscope, the retractor 223 includes at least twelve (12) strips 229 that are outwardly expanded in a radial direction to form a spherical-shaped work space or field of view for observing adjacent organs or tissues via the optical assembly 203. (See Fig. 12G). The retractor illustrated in Figure 10D likewise includes multiple strips 131 that are expanded in a radial direction to form a spherical-shaped work space for observing adjacent organs or tissues. Even assuming *arguendo* that the radially expanded strips 229 could be construed to comprise transverse projections, as admitted in the final Office Action, the retractor 223 does not satisfy the recitation of “no more than two transverse projections” that are each “arranged along a single transverse axis”, and the radially expanded strips 229 do not extend “in a uni-axial direction aligned with said single transverse axis”, as recited in independent claim 59. To the contrary, the retractor 223 clearly includes more than two strips 229 (i.e., twelve strips) that are arranged along multiple transverse axes, extend in multiple radial directions, and which are clearly not aligned with a single transverse axis. Accordingly, Moll fails to satisfy each of the features recited in independent claim 59.

Moreover, the Applicant submits that one of ordinary skill in the art would not be motivated to modify the endoscope 201 disclosed in Moll to arrange the expanded strips 229 along a single transverse axis so as to extend in a uni-axial direction. It is well established that “[t]o establish a *prima facie* case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. . . .” Also, a “prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention” (MPEP § 2141.02.VI), and the Patent Office recognizes that “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” (MPEP § 2143.01.V).

As indicated above, Moll discloses an endoscope 201 including a retractor 223 that is expanded to retract organs obstructing the field of view from the distal end of the optical assembly”, and that the expanded retractor 223 “retracts organs or tissues that would otherwise obstruct the view from the optical assembly”. The expanded retractor 223 thereby retracts the organs or soft tissues to provide a spherical work space or field of view such that adjacent organs or tissues can be observed and directly visualized via the optical assembly 203 positioned within the spherical work space formed by the radially expanded strips 229. As should be appreciated,

limiting the number of expanded strips 229 to “no more than two” and positioning each of the radially expanded strips 229 “along a single transverse axis” so as to extend “in a uni-axial direction aligned with said single transverse axis” would not result in the formation of a work space or field of view between the expanded strips 229 sufficient to allow for observation and direct visualization of adjacent tissues via the optical assembly 203. To the contrary, limiting the number of expanded strips 229 to “no more than two” and aligning the strips “along a single transverse axis” would provide a very narrow and confined work space, and the only structures that would be observable via the inner optical assembly 203 would be the opposing inner surfaces of the strips 229. Such a result would obstruct observation/viewing of adjacent organs/tissues via the inner optical assembly 203, and the Moll device would therefore not function as intended to provide unobstructed observation/visualization of adjacent tissues positioned within the spherical work space formed by the radially expanded strips 229.

When the teachings of Moll are taken as a whole and considered in their entirety, one of ordinary skill in the art would not limit the number of strips to “no more than two”, and would likewise not arrange each of the strips 229 “along a single transverse axis” so as to extend “in a uni-axial direction”, for to do so would fail to provide the unobstructed spherical work space or field of view necessary to properly observe adjacent tissues via the inner optical assembly 203. Accordingly, one of ordinary skill in the art would not be motivated to modify Moll to arrive at the invention recited in independent claim 59, and a *prima facie* case of obviousness has therefore not been established with regard to the rejection of the independent claim 59.

Dependent claims 55-58, 60-63, 65, 68 and 74 are submitted to be patentable for reasons in addition to those supporting the patentability of independent claim 59. As set forth in the Advisory Action, the previous grounds of rejection regarding claims 94-97 have been withdrawn (page 2), and claims 94-97 have been indicated as “allowed” (page 1). However, the Applicant notes that claims 94-97 are currently written in dependent form, and that claim 94 recites subject matter similar to that recited in allowed independent claims 66 and 69. The Applicant presumes that claim 94 would be in condition for allowance if rewritten in independent form, and that dependent claims 95-97 (which depend from claim 94) would also be in condition for allowance.

MPEP §2142 states that “[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness”, and . . . that ‘rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’”

The Applicant notes that claim 63 recites an actuator mechanism comprising a first portion coupled to an actuator member and a second portion coupled to the sleeve member and engaged with the first portion, and “wherein relative rotation between said first and second portions imparts relative linear displacement between said actuator member and said sleeve member to cause said distal portion of said sleeve member to reform from said initial configuration toward said expanded configuration”. Even assuming arguendo that the optics assembly 203 of Moll could be construed as a second portion of an actuator mechanism that is coupled to the retractor 223, Moll fails to disclose or suggest “a first portion coupled to an actuator member”, and does not set forth any type of actuator mechanism wherein “relative rotation” between first and second portions imparts relative linear displacement between the optics assembly 203 and the retractor 223 to transition the strips 229 to an expanded configuration. Instead, the strips 229 are expanded by sliding the slidable hub 227 axially along the optics assembly 203, which in turn causes the strips 229 to outwardly expand. (See Fig. 12G). However, Moll does not in any way teach or suggest that relative rotation between first and second portions imparts relative linear displacement between the optics assembly 203 and the retractor 223 to expand the strips 229. Additionally, the grounds of rejection set forth in the final Office Action with regard to claim 63 merely constitute a restatement of the claim language (See page 5, lines 10-13). However, such grounds do not provide the requisite “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Furthermore, claim 74 recites that the deformable distal portion is “at least partially formed of a shape-memory material” and reformed toward the expanded configuration in response to the imposition of stress and automatically reformed back toward the initial configuration upon removal of the stress. The Applicant has thoroughly reviewed Moll and has not found any reference or indication that any portion of the retractor 223 is formed of a shape-memory material, and the final Office Action does not cite to any language in Moll that discloses such a feature. Accordingly, the rejection of claim 74 as being obvious over Moll is improper.

In summary, the Applicant submits that independent claim 59 and the claims depending therefrom recite various features that are not disclosed or suggested by Moll, and the grounds of rejection set forth in the final Office Action fail to establish a *prima facie* case of obviousness.

Respectfully submitted,

By: 

Brad A. Schepers; Reg. No. 45,431